Reconsideration of the above application is respectfully requested.

There are 17 claims pending in this application. These are claims 1 - 17. Claims 1-5, 8-10 and 12-17 have been rejected. Claims 6, 7 and 11 have been withdrawn from consideration.

By the above amendments, Applicant has cancelled claims 1, 6, 7, 11, 15, 16 and 17, and have added new claims 18, 19, 20 and 21.

The above amendments add no new matter to this case. New claim 18 has been added to replace cancelled claim 1 and new claim 19 has been added to replace cancelled claim 15. New claims 20 and 21 have been added to replace, respectively, cancelled claims 16 and 17. New claim 18 differs from claim 1 in that it refers solely to elected subject matter and also in that it reflects revisions that have been made to the original language of claim 1 in response to the Examiner's rejection of that claim under 35 U.S.C. § 112. New claims 20 and 21 differ from claim 16 and 17, respectively, in that they reflect revisions that have been made to the original language of claims 16 and 17 in response to the Examiner's rejection of those claims under 35 U.S.C. § 112. New claim 19 differs from claim 15 in that it refers only to elected subject matter. Support for the subject matter of new claims 18, 19, 20 and 21 can be found, respectively, in claims 1, 15, 16 and 17, and also on page 1 of the specification (which refers to the utility of CRF receptor antagonists in treating immune suppression).

Applicant reserves her right to prosecute the nonelected subject matter that has been cancelled from this application, by the above amendments, in subsequent divisional applications. Such subject matter has been cancelled solely for the purpose of complying with the Examiner's restriction requirement and expediting prosecution of the remaining subject matter in this application.

In the Office Action, the Examiner restricted the subject matter of this application to one of four groups, Groups I - IV that are set forth on page 2 of the Office Action. Applicant confirms her election to prosecute the subject matter of Group I that was made by her undersigned attorney on July 7, 1997. This election is made without traverse.

The Examiner rejected claims 1-5, 8-10, 12-14, 16, and 17 under 35 U.S.C. § 112, paragraphs 1 and 2, for the following reasons, each of which is discussed separately below.

The Examiner stated that the phrase in claim 1 that begins with the word "wherein" on page 49, at line 16-18, does not make sense because an alkyl group cannot contain multiple bonds. Applicant respectively submits that the phrase in question, which reads, "wherein each of the C_1-C_4 alkyl groups... may optionally contain one or two double or triple bonds", would be understood to one of skill in the art to mean "wherein one or two of the carbon-carbon single

bonds of each of the C_1-C_4 alkyl groups... may optionally be replaced with a carbon-carbon double or triple bond". Applicant has substituted the latter phrase for the one objected to by the Examiner in drafting new claim 18. Applicant, in drafting new claim 18, has made similar revisions to the claim 1 language that appears on page 49 at lines 19-26 and on page 50 at line 18.

The Examiner stated that "R^2 = benzyl" in claim 2 is not provided for in claim 1. Applicant respectfully submits that "R^2=benzyl" is specified in claim 1. The definition of R^2 on page 49, at lines 20-21, specifies that R^2 can be "(C_1 -C_4 alkylene)aryl, wherein ... the aryl moiety of said (C_1-C_4 alkylene)aryl is selected from phenyl...".

The Examiner stated that the material beginning on page 49, at line 24, and ending with the word "alkanoyl" on line 28 of the same page has no function and should be deleted, reasoning that the definition of R^2 is closed by the "or" that appears on line 20, and that the definition of "aryl" ends at the end of line 23. Applicant respectfully submits that the text on page 49, at the begining of line 24, that begins with the phrase "C_3-C_8 cycloalkyl..." is a proper and logical continuation of the definition of R^2. The semicolon that precedes this phrase at the end of line 23 simply serves, as recognized by the Examiner, to complete the definition of "aryl". The fact that no additional substituent was named after the semicolon indicates that the text beginning immediately after it, i.e., beginning on line 24 with the above phrase, is a continuation of the definition of R^2. Applicant respectfully submits that the use of the conjunction "or" on line 20 of page 49 does not negate the continuation of the definition of R^2. It merely illustrates a stylistic preference to connect two like groups (i.e., the aryl and (C_1-C_4alkylene)aryl groups), in view of the fact that the definition "aryl" that follows applies to both groups. Applicant, nevertheless, has inserted the phrase "or R^2 is" before the phrase in question in drafting new claim 18.

The Examiner also cited, as support for his §112 rejection, Applicant's use of the language "carbocyclic ring" to describe a ring formed by either $-NR^1R^2$ or $-CR^1R^2R^{10}$, as referred to on page 50, at line 5. Applicant respectfully submits that the characterization of such rings as "carbocyclic" was an oversight with respect to $-NR^1R^2$, which obviously must contain at least one heteroatom. She has amended this language in new claim 18 to state explicitly what would have been obvious to one of skill in the art from the original definition in claim 1, which is that $-CR^1R^2R^{10}$ can form a carbocyclic ring while $-NR^1R^2$ can form a ring containing one heteroatom.

The Examiner also objected to Applicant's use of the phrase "C_1-C_3 thioalkyl", stating that this term is ambiguous because it could mean "C_1-C_3 alkylthio" or "mercapto C_1-C_3 alkyl." Applicant has amended this phrase to read "C_1-C_3 alkylthio". Applicant respectfully submits that this revision adds no new matter to the application because one of skill in the art would have understood that the revised definition is the one that was intended by the original language. Specifically, one of skill in the art would have known that the original language was not intended to mean "S-alkyl" because this would result in there being only one bond to the sulfur atom. One of skill in the art also would have known that the original language was not intended to mean "SH alkyl" because the group "SH" is referred to as "mercapto" rather than as "thio".

The Examiner also stated that the phrase at the end of claim 3, on page 51, at line 30-31, which reads, "wherein . . . triple bond", has no antecedent basis in either the definition of R^5 in claim 1 or in the specification. Applicant, by the above amendments, has included such an antecedent basis in the definition of R^5 in new claim 18, which replaces original claim 1.

The Examiner also objected to the use Applicant's of the phrases "such as" and "including but limited to . . . CRF", which appear in claims 16 and 17. By the above amendments, Applicant has deleted all occurances of these phrases from new claims 20 and 21, which have been added to replace claims 16 and 17.

The Examiner also stated that the scope of "option (a)" in claims 16 and 17 is unknown and cannot be determined without undue experimentation. Applicant respectfully traverses this ground for rejection, with respect to new claims 20 and 21 which have been added to replace claims 16 and 17. Option (a) of claims 20 and 21 refers to a method of treating "a disorder the treatment of which can be effected or facilitated by antagonizing CRF" in a mammal, comprising adminstering to said mammal one of the pharmaceutically active compound of claim 1. Applicant respectfully submits that this language is clear and definite, albeit broad in scope, and is sufficiently supported by the specification. The pharmaceutically active compounds of claim 1 are described in detail on pages 1-12 of the specification, and methods by which such active compounds can be prepared are described in detail on pages 16-31 and 35-47 of the specification. The specification also sets forth in detail, on pages 14-16, the pharmaceutical compositions and methods of treatment claimed in claims 20 and 21. A description of how the foregoing claimed pharmaceutical compositions can be prepared appears on pages 33-34 of the specification. Moreover, the specification sets forth in detail, on pages 33-34, how the methods of claim 21 can be carried out by those skilled in the art. It specifies, on these pages, not only the conditions that can be treated or prevented by the administration of

a compound according to of claim 1, but also appropriate dosages and methods of administration. This description includes the various modes by which the compounds employed in the claimed methods can be administered to mammals, the pharmaceutically acceptable forms in which they can be administered, and appropriate dosages for their administration. The foregoing information is sufficient to enable one skilled in the art to practice the inventions of each of claims 20 and 21 and thus complies with the requirements of 35 U.S.C. § 112.

A specification disclosure that contains a teaching of the manner and process of making and using the invention in terms that corresponds in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. In re Marzocchi, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971). Further, the burden is on the Examiner to come forth with evidence to establish a prima facie case of non-enablement. Ex parte Hitzeman, 9 U.S.P.Q. 2d 1801, 1822 (Pat. Off. Bd. App. 1988); In Re Armbruster, 185 U.S.P.Q. 152, 153 (C.C.P.A. 1975); In re Marzocchi, 169 U.S.P.Q. at 370.

Applicant further submits that one of skill in the art would find the phrase "disorders the treatment of which can be effected or facilitated by antagonizing CRF", as used in "option (a)" above, to be clear and definite. There are certain disorders that are known in the art, the treatment or prevention of which can be effected or facilitated by antagonizing CRF. Several of these are referred to in the present specification. As more is learned about the mechanisms of various disorders, additional disorders will become part of this category. However, the meaning and scope of the language of "option (a)" is now and will remain clear and definite to those of skill in the art.

The Examiner also objected to several of the specific disorders or categories of disorders mentioned in claims 16 and 17. Applicants have addressed many of these issues in drafting new claims 20 and 21. Specifically, Applicant, in drafting claims 20 and 21, has deleted the following phrases: "pain perception such as", "psychosocial dwarfism", "mood disorders such as", "neurodegenerative diseases", "gastrointestinal disorders", "infertility", and "senile dementia of the Alzheimer's type". They have also replaced the phrase "human immunodeficiency virus infections" with "acquired immune deficiency syndrome (AIDS)", and replaced the phrases "immune dysfunctions" and "stress-induced immune dysfunctions" with "immune suppression".

The Examiner also objected to the inclusion of "cancer" and "chemical dependencies and addiction" as indications that can be treated with the compounds of claim 1. The Examiner stated, "there is no compound effective against cancer, and given the widely different cause for cancer, there is no reason to think such agent can be found." Applicants respectfully traverse this ground for rejection.

Applicant respectively submits that one of skill in art would not find it incredible or wholly inconsistent with contemporary knowlege in the art that a chemical compound could be used as a therapeutic agents against several, if not many types of cancer. (See In re Langer, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974), and the PTO's Guidelines for Examination of Applications for Compliance with the Utility Requirement (December, 1994)). While there may exist several different causes of human cancers, there are common growth characteristics that apply to malignant tumors in general. There are also several known chemotherapy agents that are useful against many types of cancer. While the mechanism for different chemotherapy agents may differ, they nevertheless have in common the fact that they destroy malignant cells without substantially interfering with the growth of normal cells.

Treatment of cancer with the compounds of the present invention can easily be distinguish from the facts of In re Ferens, 163 U.S. P.Q. 609 (C.C.P.A. 1969) and In re Schmitt and Wilhelm, 153 U.S.P.Q 640 (C.C.P.A. 1967), both of which were cited by the Examiner. The Court of Customs and Patent Appeals, in In re Ferens, held that the patent applicant had not provided sufficient evidence of the utility of his claims directed to hair growth compositions and methods. Contrary to the state of the art of hair growth promotion in 1969, when there was no know effective treatment for baldness, there are today several effective cancer chemotherapy agents that are used to treat a wide variety of cancers. In In re Schmitt and Wilhelm, the Court of Customs and Patent Appeals held that there was not sufficient support in a patent application for the utility of claimed compounds that were stated in the specification to assist liver function in "hepatic disturbance." Applicant respectively submits that the category of "hepatic disturbance" encompasses a large number of mechanistically diverse illnesses that, contrary to human cancer, do not share a central mechanistic feature that renders them treatable by similar agents.

Applicant further submits that one of skill in the art would not find it incredible or wholly inconsistent with the state of the art that the CRF receptor antagonists of new claim 18 could be used generally to treat chemical dependencies and addictions. As indicated on page 1

of the specification, such utility of CRF receptor antagonists was known in the art at the time the present application was filed.

The Examiner likened the statement of utility of the present case to that of In re Ziegler, 26 U.S.P.Q. 2d 1600 (Fed. Cir. 1993) and In re Kirk and Petrow, 153 U.S.P.Q. 48 (C.C.P.A. 1967). Applicant respectfully submit that the present situation is also easy distinguishable from both of these court decisions. In re Kirk and Petrow, the statement of utility that the court held to be insufficient under §§101 and 112 was a broad statement that the claimed compounds exhibited "biological activity" or "biological properties". No specific disorders or categories of disorders were referred to in the specification. In In re Ziegler, the Federal Circuit affirmed the lower court's decision that the foreign priority document for a U.S. application lacked a statement of practical utility for the claimed polypropylene product, where such document described certain physical characteristics of the product (e.g., that it could be pressed into a flexible film and was "plastic like"), but did not refer to any practical utility, categorically or otherwise.

Applicants respectfully submit that all pending claims, as amended, comply fully with the provisions of 35 U.S.C. §112. Applicants therefore request that all pending claims, as amended, be allowed to issue.

Respectfully submitted,

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